

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets

(11)

EP 0 700 668 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
13.03.1996 Bulletin 1996/11

(51) Int. Cl.⁶: A61F 2/00, F16K 31/08

(21) Application number: 94306675.3

(22) Date of filing: 12.09.1994

(84) Designated Contracting States:
DE FR GB IT SE

(71) Applicant: Davis, Philip J.
Honolulu, Hawaii 96825 (US)

(72) Inventor: Davis, Philip J.
Honolulu, Hawaii 96825 (US)

(74) Representative: Feakins, Graham Allan et al
RAWORTH, MOSS & COOK
RAWORTH HOUSE
36 Sydenham Road
Croydon, Surrey CRO 2EF (GB)

(54) Intraurethral magnet valve

(57) An intraurethral magnet valve for insertion into the urethra of a person suffering from incontinence has relief valve (10) comprising a non-ferromagnetic housing (11) containing a valve member (18) with a permanent magnet (19) encapsulated within a non-magnetic material magnetisably seating on a valve seat (16) of high magnetic permeability ferromagnetic nature. Retaining flanges (13) integral with the housing prevent escape of the valve element when valve is open. A manually held permanent switching magnet (21) is used to induce magnetic torque and attraction on the valve element causing it to rotate within the tubular housing thereby lifting same from the valve seat and opening the passageway there-through and through the urethra.

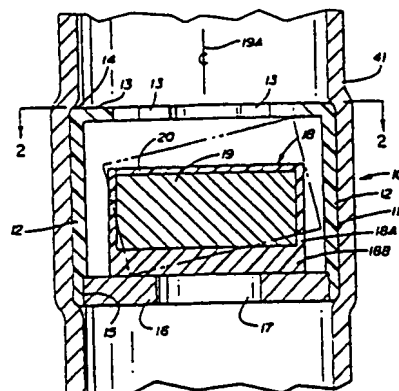


FIG. 1

EP 0 700 668 A1

Description

This invention relates to intraurethral magnetic valves that are used to provide a valving means for individuals suffering from an inability to control their bladder functions by substituting a mechanical magnetic actuated valve to control the flow of urine.

Known devices of this type have relied on a wide variety of different magnetic valve configurations that attempt to control the fluid flow from the bladder. Examples of these can be divided into two basic designs. Firstly, there are ferromagnetic spheres or slugs which seal an aperture by attraction to one or more fixed permanent magnets within a valve housing and are drawn away from the aperture by a strong permanent magnet or electromagnetic field induced by a hand held magnet located outside the valve housing, see for example US-A-3,731,670 and US-A-5,004,454.

The second group is characterised by permanent magnets bonded to nonmagnetic check valves which are drawn to seal an aperture by attraction to a ferromagnetic element comprising all or part of the aperture or are resiliently held in a closed position on the aperture by a spring. These checks are drawn in a straight linear motion away from the apertured valve seat by a hand held magnet outside the valve housing, see for example US-A-3,812,841 and US-A-5,140,999.

In US-A-3,731,670 a corporeal fluid control using a binary magnetic duct valve is disclosed wherein a mounting tube has two spaced magnets with a steel ball valve element therebetween. The ball valve element is selectively attracted to each of the magnets defining an open or closed state depending on which magnet the ball is engaged. The ball is reciprocated within the structure by an external magnetic force.

US-A-5,004,454 is directed to an auxiliary intraurethral magnetic valve wherein a plastics tube defines the valve body and a valve seat. A valve element of a ferromagnetic material is held in sealing relation against the valve seat by a spring associated therewith. The valve is opened by imposing a magnetic force on the valve element drawing same away from the seat and stretching the spring.

The first type of device tends to suffer from an intrinsic difficulty in balancing the magnetic force needed for adequate sealing with the need for reasonable operational range of the activation magnet.

Since magnetic forces are highly nonlinear, decreasing very rapidly with distance from the magnetic poles; when a ferromagnetic ball or slug is held against an aperture by a permanent magnet element the respective switching magnet must be either very large or very close to induce the required force. The slug checks that are drawn to the side of the housing encounter high sidewall friction forces which are induced increasingly as the angle between the housing centre line and the line of approach of the switching magnet increases.

In US-A-3,812,841 a urethra magnetic valve structure has a valve element positioned on a movable mag-

netic core cylinder. The valve element is held in closed position by an attached spring. Inducing a high electromagnetic force from outside the body will move the magnetic core cylinder and valve element attached thereto opening the valve.

In US-A-3,812,841, the valve check movement is constrained by the housing to a straight line which necessitates that unless the switching magnet approaches with its axis directly aligned on the centre line the force will draw the check against the sidewall imparting torque induced friction decreasing the effectiveness and movement of the check within the valve housing.

US-A-5,140,999 is directed to an implantable valve structure in which the valve element extends well within the bladder for increased lateral operational movement. The valve element has a compression spring engaging same in a closed or checked position. Upon inducement of an outside magnetic force the magnetisable member on the free end of the valve element within the bladder is displaced to the side moving the respective valve element off its valve seat opening the valve. No accommodation is made for bladder neck movements or changes in bladder inflation which may cause unwanted movements of the free end of the valve element.

According to the present invention there is provided a magnetic valve comprising a tubular housing of non-magnetic material, a valve element within said housing and an apertured valve seat sealingly engageable by said valve element, characterised in that said valve element comprises a permanent magnet and a non-ferromagnetic means for spacing said permanent magnet with respect to said valve seat, said valve element being normally magnetically attracted to said valve seat thereby occluding and sealing same and there being separate magnetic means for opening said valve by imposing a magnetic field on said valve element to overcome the magnetic attraction to said valve seat, pivoting said valve element away from sealing relation with said valve seat.

For a better understanding of the invention, and to show how the same may be carried into effect, reference will now be made by way of example, to the accompanying drawings, in which:-

Figure 1 is a sectional view taken through an intraurethral magnetic valve shown within a placement catheter;

Figure 2 is a section on lines 2-2 in Figure 1;

Figure 3 is a sectional view of an alternative form of the valve, in a closed position;

Figure 4 is a sectional view of the form shown in Figure 3 in an open position;

Figure 5 is a section on lines 5-5 in Figure 3;

Figure 6 is a section on lines 6-6 in Figure 3;

Figure 7 is a side view with portions in sections showing a catheter placement device for the valve;

Figure 8 is a diagrammatic sectional view showing the device implanted for controlling flow through the urethra; and

Figure 9 is a sectional view of another form of the device, showing an encapsulated magnet.

Referring to Figures 1 and 2 of the drawings, an intraurethral relief valve assembly 10 comprises a cylindrical non-magnetic housing 11 having a continuous side wall 12. A plurality of annularly spaced retaining flanges 13 extend inwardly from a perimeter edge 14 of the cylindrical housing 11 defining the sidewall 12. A recessed area 15 in the sidewall 12 extends inwardly from its free end defining a mounting surface for registration with a ferromagnetic valve seat 16. The valve seat 16 has a cylindrical aperture at 17 concentric within the cylindrical housing 11. A valve element 18 comprises a cylindrical magnet 19 encapsulated within a generally U-shaped non-magnetic capsule 18A of biocompatible material having a thicker base portion 18B adjacent the valve seat 16 and an oppositely disposed closer 20 adhesively fixed to the magnet 19.

The valve element 18 is normally attracted to the ferromagnetic valve seat 16 for sealing registration therewith occluding the cylindrical aperture at 17, thereby closing the valve 10. The magnet 19 is magnetised along its central line axis.

The flanges 13 may also be used as engagement points for gripping and positioning the valve assembly 10 within the body lumen or placement catheter.

It is important that the magnet 19 has high coercive force and high residual flux density to achieve the proper durability and sealing ability.

Figure 1 shows the valve assembly 10 in the closed position with the valve element 18 shown in broken lines indicating the free range of travel required during operation and thus the relative clearance of the valve element 18 within the housing 11 when open.

This valve open position occurs upon activation of the valve element 18 by a switching magnet 21 (Figure 8). The magnet 21 is of a generally bar configuration in this example, having been magnetised along its longitudinal centre line axis A. When the magnet 21 is brought into close proximity to the valve element 18 as indicated with their respective magnetic centre lines in a non-axial alignment, magnetic torque is induced on the valve element 18. The misalignment of the respective magnetic fields of the switching magnet 21 and the magnet 19 within the valve element 18 induces the rotation of the valve element 18 to reposition within the housing 11 as shown in broken lines in Figure 1, thus opening the valve assembly 10 for passage of fluid. The valve element 18 should be of a sufficient size to prevent excess rotation that would and could lead to a potential to jam or impinge against the inner surface of the housing 11, thus preventing reseating of the valve element 18 in the aperture occluding position by the limited magnetic attraction available.

The retaining flanges 13 limit the relative movement of the valve element 18 within the housing so that the required range of magnetic attraction between the valve element 18 and the valve seat 16 is sufficient to return the

valve element 18 to the aperture occluding position upon deactivation i.e. removal of the switching magnet 21 (as shown in solid lines in Figure 1).

The valve element 18 also acts as a high pressure relief element, with relief pressure determined by the magnitude of the attraction forces between the valve element 18 and valve seat 16 at the relative separation distance imposed by the non-ferromagnetic base portion 18B of the capsule 18A. The axial symmetry of the valve seat 16 and the magnet 19 within the valve element 18 limits magnetic attractive forces that tend to draw the valve element 18 against the inner walls of the housing 11 and thus limits friction between the housing 11 and valve element 18. This symmetry also provides uniform distribution of closure force around cylindrical aperture at 17 in the valve seat 16. Relief pressure may be altered by varying any combination of the non-ferromagnetic capsule base 18B thickness, the mass of the valve seat 16, the magnetic permeability of the valve seat 16, or the mass of the magnet 19, its respective magnetic aspect ratio (length to diameter) or its magnetic residual flux density in the valve element 18, and the aperture area at 17 of the valve seat 16.

The switching magnet 21 may be positioned at any angle relative to the valve element 18 and enclosed magnet 19 centre line axis indicated at 19A.

Referring now to Figures 3-6, an alternative form is shown wherein a cylindrical valve housing 22 has a cut through its sidewall at 23 inwardly of its respective ends 24 and 25. Retaining flanges 26 and valve seat 27 apertured at 27A are identical to those described above.

A hinged valve element 28 is of a similar construction as that of said valve element 18, having an encapsulated magnet 29 adhesively bonded within a biocompatible material and a non-ferromagnetic capsule 29A characterised by a thicker base portion 30.

The hinged valve element 28 has a mounting plate closure 31 that is secured to the encapsulated magnet 29 opposite the base portion 30. The mounting closure plate 31 extends to form a knuckle 32 configured thereon for pivotal registration of a hinge pin 33 that extends through the knuckle 32 and around the exterior surface of the cylindrical valve housing 22 in a mounting groove 34, best seen in Figures 5 and 6. The hinged valve element 28 is normally in the closed position indicated in Figure 3 with the magnetic attractive forces of the encapsulated magnet 29 reactive to the apertured valve seat 27.

In use, under the magnetic pull from the switching magnet 21, the hinged valve element 28 is pivoted to an open non-occluded position as shown in Figure 4 allowing for free flow of fluid through the valve. In this example, when the switching magnet 21 is brought into close proximity to the valve, with its respective centre line A in or closely aligned to an activation plane defined by the centre line 22A of the valve housing 22 and the perpendicular bisector of the straight portion of the hinge pin 33 at 33A and the closest end of the switching magnet 21 having appropriate magnetic polarity to the outflow side of

the magnet 29, indicated by arrows "OF" in Figure 4, then two valve open conditions are possible.

The first valve open position is with the switching magnet 21 on the outflow side of the magnet 29, the magnetic attraction therebetween overcomes that of said valve seat 27.

The second condition for a valve opening is when the switching magnet 21 is on the inlet flow (indicated by arrows "IF") of the magnet 29, the magnetic repulsion exceeds attraction between the magnet 29 and the valve seat 27. Additional force tending to open the valve is provided by magnetic torque induced by the valve element 28 and the misalignment of the switching magnet 21 and the magnet fields of the valve element 28. Thus the switching magnet 21 may be anywhere in the activation plane, but should not approach with its midplane coincident with the midplane of the encapsulated magnet 29 where the effective working distance is least.

Figure 7 shows an example of a placement vehicle for the valve assembly 10. In this example, chosen for illustration, a modified catheter 41 can be seen having an elongate tubular body member 42 with longitudinally spaced retention bulges 43 and 44 thereon. A portion of the catheter 41 within the prostatic urethra 38 is constructed to resist collapse and be held within by the retaining bulge 43 within the bladder 40 and adjacent the external sphincter 37 as illustrated by the bulge 44 extending as near as possible thereto within the bulbous urethra 36.

The valve 10 is positioned within the catheter 41 adjacent the distal end at 52. The catheter 41 is designed to be easily placed and removed much like known internal catheters.

The valve assembly 10 within the catheter 41 is flow orientated so that the respective valve seats 16 and 27 illustrated are adjacent the upstream flow indicated by the respective inflow arrows IF shown in Figure 4.

In Figure 8, a partial cross-section through a human abdomen 35 illustrates the positioning of the valve assembly 10 within the patient. The abdomen 35 contains the bulbous urethra 36, external sphincter 37, prostatic urethra 38, prostate 39 and bladder 40.

Referring now to Figure 9, another form is illustrated, wherein a cylindrical housing 50 has a valve element 51 within, the valve element 51 being defined by a permanent magnet 46 encapsulated within a coating or plating of biocompatible materials CA adhered to a non-ferromagnetic cylindrical pad 47. The pad 47 is engageable in sealing relation against a valve seat 48 apertured at 49 corresponding to the above described valve seats 16 and 27 shown in respective valve element configurations 18 and 28.

It will be appreciated that the valve assembly 10 can be used in other environments not exclusive to the human body where reliable self-contained remotely actuated valves are required.

Claims

1. A magnetic valve comprising a tubular housing (11, 22, 50) of non-magnetic material, a valve element (18, 28, 51) within said housing and an apertured valve seat (16, 27, 48) sealingly engageable by said valve element, characterised in that said valve element comprises a permanent magnet (19, 29, 46) and a non-ferromagnetic means (18B, 30, 47) for spacing said permanent magnet with respect to said valve seat, said valve element being normally magnetically attracted to said valve seat thereby occluding and sealing same and there being separate magnetic means (21) for opening said valve by imposing a magnetic field on said valve element to overcome the magnetic attraction to said valve seat, pivoting said valve element away from sealing relation with said valve seat.
2. A magnetic valve according to claim 1 and comprising spaced flanges (13, 26) extending inwardly of said housing in oppositely disposed spaced relation to said valve seat to retain said valve element within said housing.
3. A magnetic valve according to claim 1 or 2, wherein said permanent magnet and said non-ferromagnetic means are cylindrical.
4. A magnetic valve according to claim 1, 2 or 3, wherein said non-ferromagnetic means comprises a non-ferromagnetic material of a predetermined thickness secured to said permanent magnet and having a planar surface to provide the fluid seal between said non-ferromagnetic means and said valve seat.
5. A magnetic valve according to any one of the preceding claims, wherein said means for opening said magnetic valve comprises a permanent magnet (21) having a longitudinal axis (A) along which it is magnetised.
6. A magnetic valve according to any one of the preceding claims, wherein said valve element is hinged within said housing by means of a mounting hinge (32) integral with said valve element and a pivot pin (33) engaging said valve element with said housing.
7. A magnetic valve according to any one of claims 1 to 6, wherein said valve element is free to tilt within said housing without fouling sidewalls thereof.
8. A magnetic valve according to any one of the preceding claims, wherein said permanent magnet (19, 29, 46) is totally encapsulated.

9. The magnetic valve according to claim 8, wherein said encapsulated magnet comprises a biocompatible coating and plating and said means for spacing said permanent magnet (46) with respect to said valve seat (48) comprises a non-ferromagnetic pad (47) secured to said permanent magnet to impart a fluid seal between said magnet and said valve seat. 5
10. A magnetic valve according to any one of the preceding claims, wherein the valve is an intraurethral valve. 10
11. An intraurethral valve according to claim 10 and further comprising means (Fig. 7) for securing said magnetic valve within the urethra of a person, including a contoured placement catheter (41) having elongate tubular body member (42) having portions of longitudinally-spaced retention bulges (43, 44) for positioning and securing said catheter within the person in communication with bladder and urethra. 15
20

25

30

35

40

45

50

55

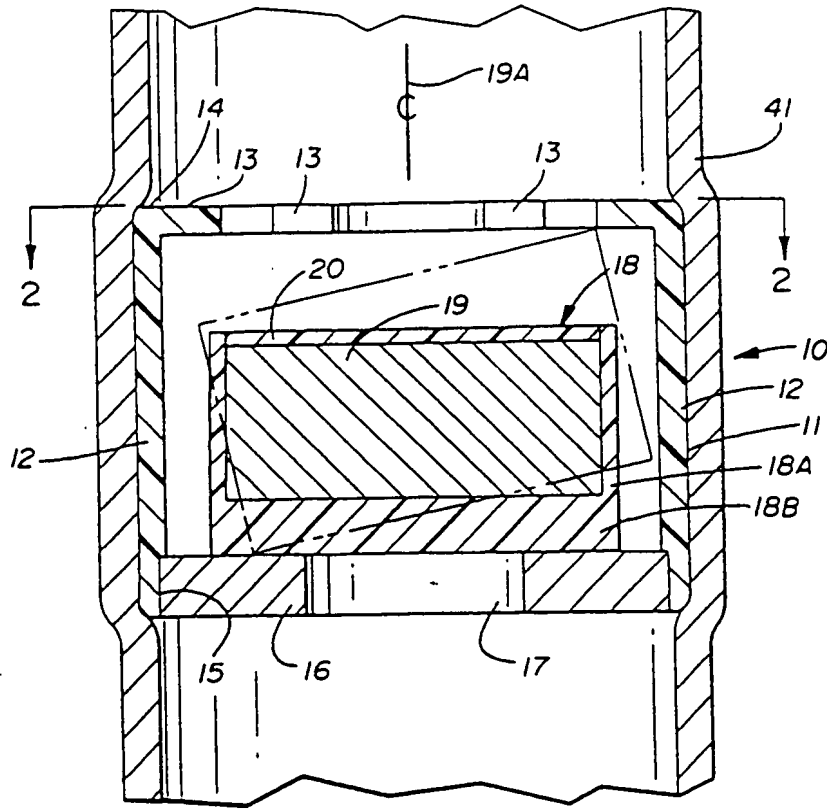


FIG. 1

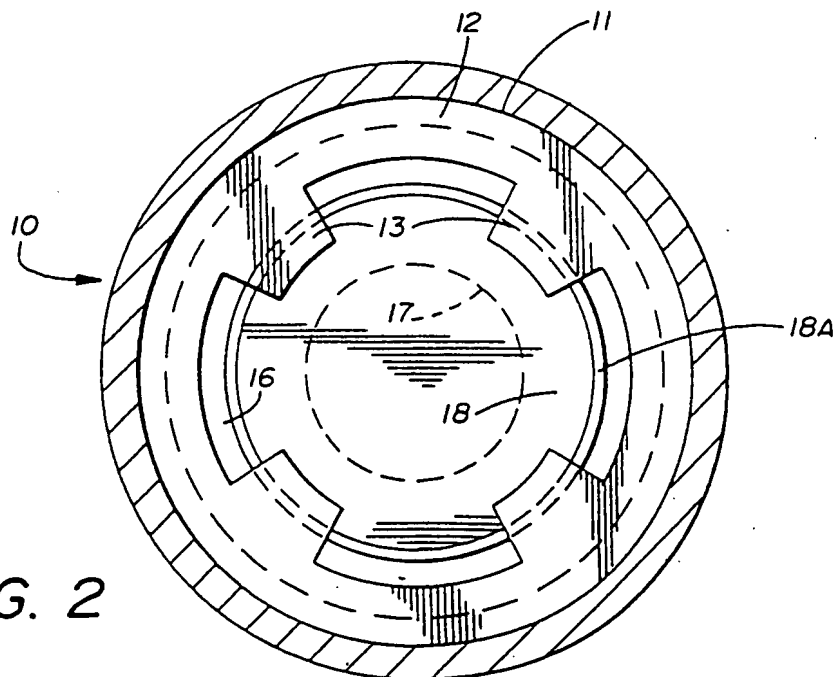


FIG. 2

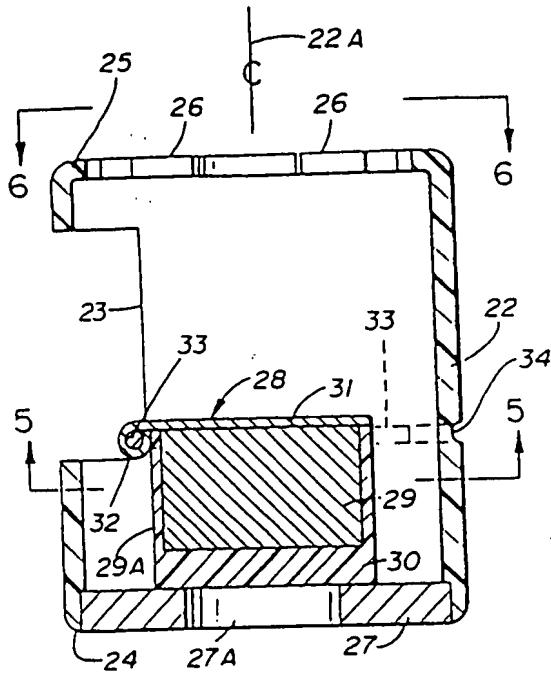


FIG. 3

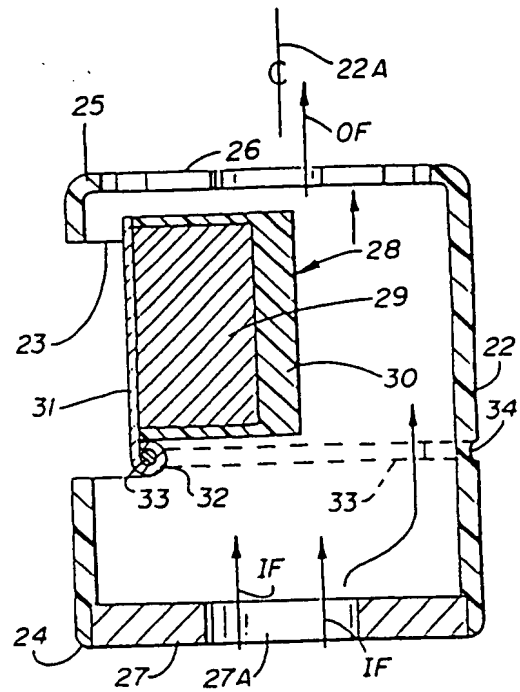


FIG. 4

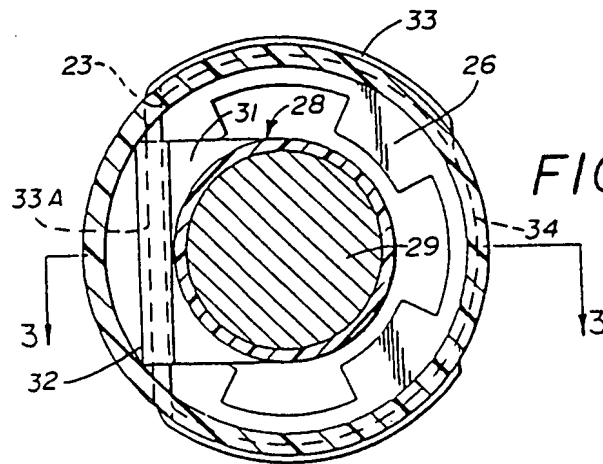


FIG. 5

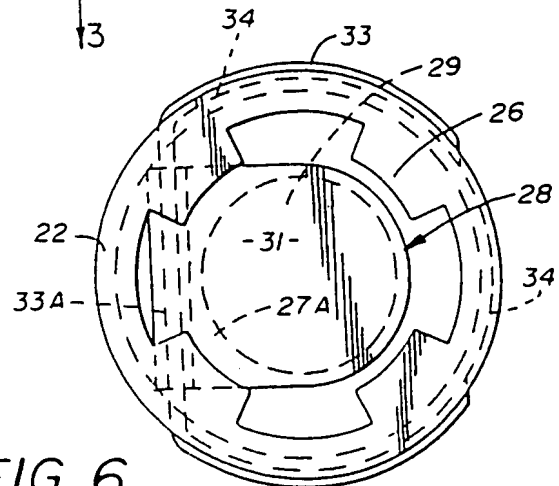


FIG. 6

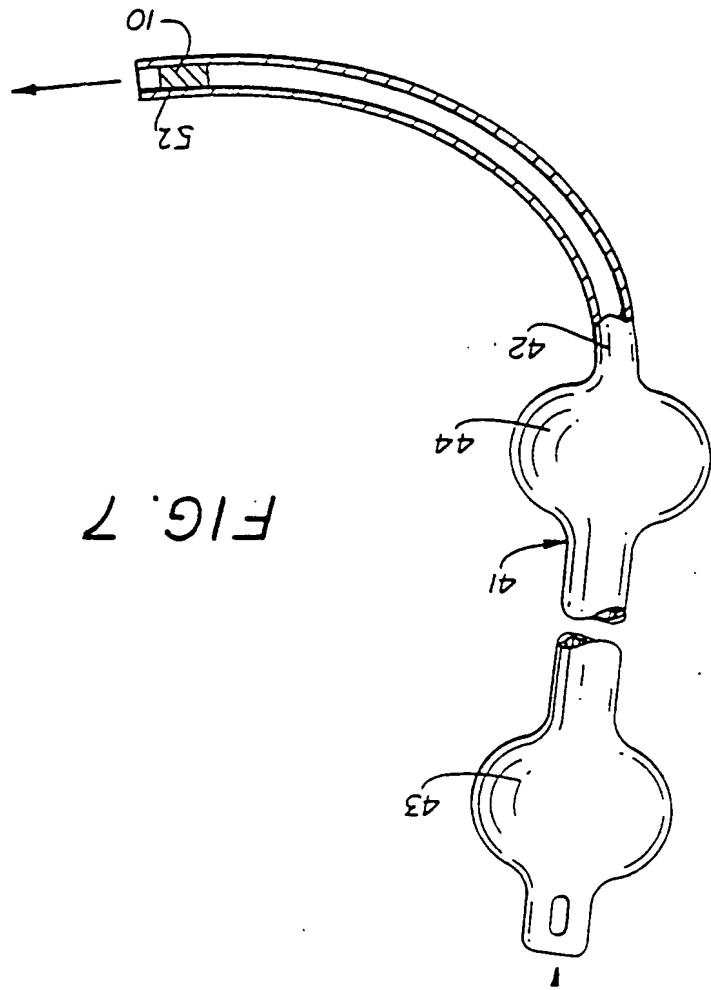
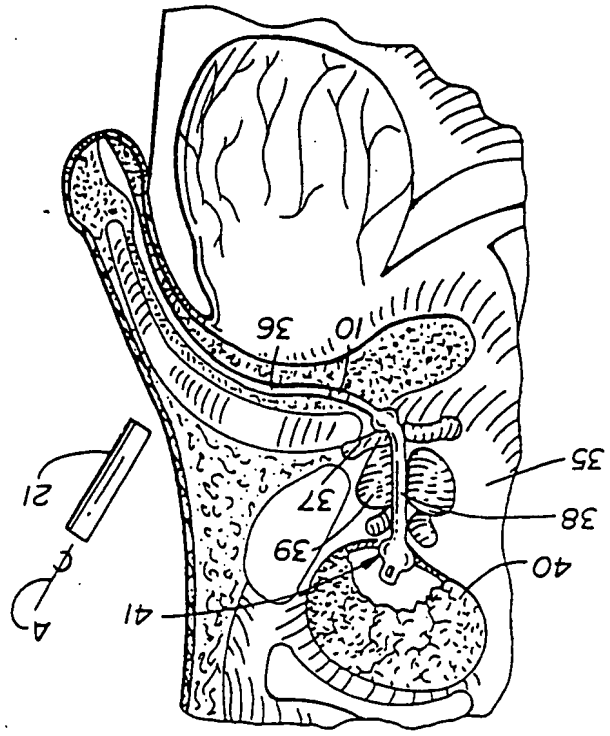


FIG. 8



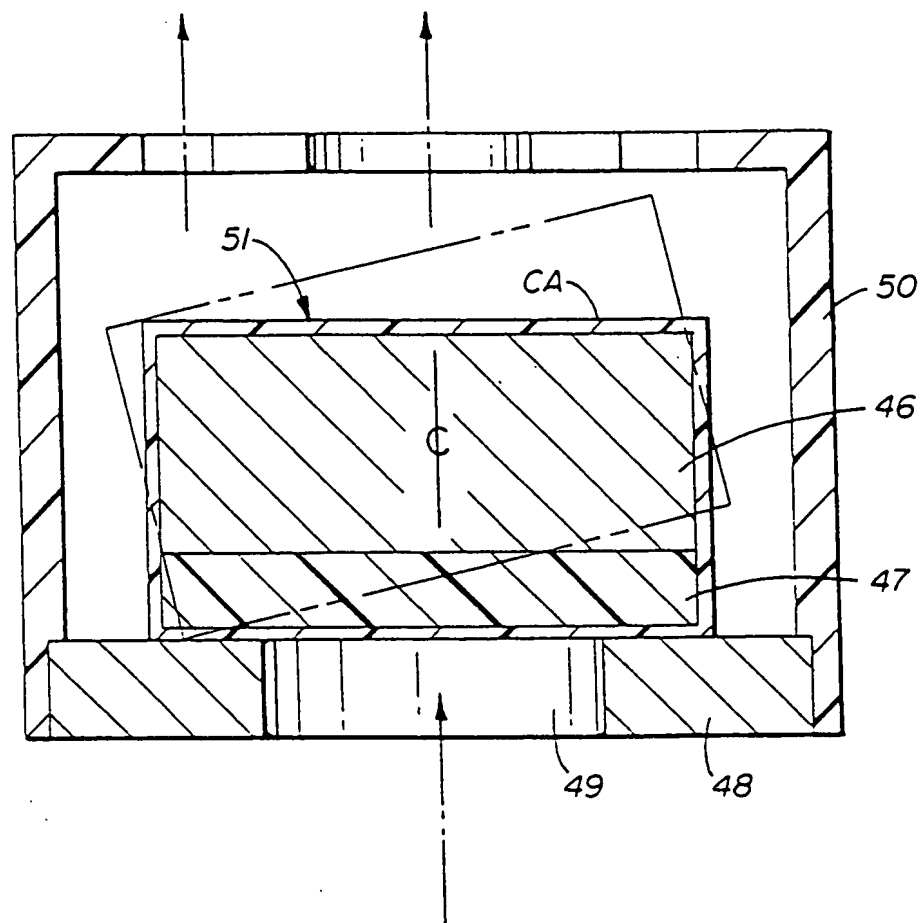


FIG. 9